

REMARKS

The amendment, filed in response to the Office Action mailed October 8, 2008, is believed to fully address all issues raised in the Action. A favorable reconsideration is respectfully requested.

Applicants thank the Examiner for granting a telephonic interview on November 21, 2008 and providing helpful advice. A Statement of Interview Substance is concurrently filed.

Claims Disposition and Current Amendments

In the previous Action, claims 1-20 and 22-24 were considered and rejected by the Office.

Upon entry of the Amendment, which is respectfully requested, claims 1-3, 5-14, 16-20, 22-24, and 54-57 will be pending in the application.

In the concurrently filed Amendment, claims 1, 16 and 18 are amended in an effort to advance the prosecution. In particular, claim 1 is amended to incorporate the subject matter of claims 4 and 15 (claims 4 and 15 are canceled accordingly) as well as to more clearly set forth the claimed subject matter. Support for the amendments may be found by original claims 4 and 15 and the disclosure in the specification.

Claim 15 is canceled without prejudice and the subject matter of claim 15 is incorporated into claim 1. New claims 54-57, directed to embodiments of the claimed subject matter, are added. Support for new claims 54-57 may be found by original claims.

The currently amended are fully supported by the disclosure of the specification, as will be discussed in detail below with respect to 35 U.S.C. § 112 rejection. No new matter is introduced and entry of the amendment is respectfully requested.

Status of Request for Three Month Suspension of Prosecution made in RCE

In the RCE filed July 14, 2008, Applicants expressly requested a suspension of prosecution for three months in order to have an opportunity for a further review of the issues. However, the current Office Action was mailed on October 8, 2008, before the expiration of the requested 3 months.

Applicants respectfully request the Office consider the above situation and give Applicants a proper opportunity which applicants originally requested by, for example, making the next action not final, should such action is not a Notice of Allowability.

Withdrawn Rejection

Applicants thank the Examiner for withdrawing the provisional nonstatutory obviousness-type double patenting rejection, in view of the amendments presented on May 14, 2008.

Response to Claim Rejections - 35 USC § 112

In the Action, claims 1-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office asserts that the limitation "a whole immunoglobulin" is not fully supported by the disclosure. The Office also states that Figures 2 and 4, which were pointed by Applicants in support of the limitation "whole immunoglobulin," are with respect to a particular hGH-PEG-IgG construct of Example 1 and are not sufficient to provide contemplation or disclosure of all conjugates now embraced by the claims. The Office also contends that the concept of "whole immunoglobulins" is not generally disclosed in the specification. In particular, the Office asserts that it is not clear what the metes and bounds of this phrase are; for example, it cannot be determined whether the recitation

"whole immunoglobulin" include single chain antibodies, chimeric antibodies, humanized antibodies, and so forth.

Applicants do not agree. Applicants respectfully submit that the specification sufficiently describes it such that one skilled in the art would understand from reading the specification that applicants had possession of the claimed conjugate comprising a whole immunoglobulin molecule defined in the claims of the instant application. The specification describes "immunoglobulins" (page 6, line 23-page 7, line 15) as well as "various antibody fragments" (page 11, lines 7-20), indicating that the Applicants contemplated and invented conjugates comprising either whole immunoglobulin (antibody) molecule or antibody fragments, and claimed conjugates comprising whole immunoglobulin molecule in the instant application.

Nevertheless, with an interests of advancing the prosecution, Applicants amend claim 1 to remove the term "whole" and specify the types of the immunoglobulins to IgG, IgA, IgD, IgE, and IgM.

Thus specific types of immunoglobulins recited in currently amended claim 1 is fully supported by original claims (particularly original claim 4) as well as the specification. The specification also provides the definition of "immunoglobulin" (page 6, line 23-page 7, line 15). In this regard, Applicants respectfully disagree with the Office's previous interpretation of the term "immunoglobulin" as it encompasses "antibody fragments" under the broadest reasonable interpretation principle. As discussed above, the specification clearly states that it was Applicants' intention and contemplation to distinguish "immunoglobulin (antibody) molecule" from "its fragments." Furthermore, the currently amended claim 1, which recites specific types

of immunoglobulins, further clarifies that the recited immunoglobulin does not encompass “antibody fragments.”

Specification Supports the Limitation “in that order”

In the regard of amendments to claim 1, Applicants note that the specification does not expressly use the term “in that order.” However, the specification does not need to have verbatim support for claim language and the specification can impliedly or expressly support claimed subject matter.

The limitation “in that order” is supported by claim 2, claim 18 and the disclosure of the paragraph bridging pages 11-12 of the specification, which describe the structural feature of the conjugate and a method of producing such conjugate as defined in claim 1. It is obvious that the method would produce the claimed protein conjugate comprising i) physiologically active polypeptide, ii) a non-peptidic polymer, and iii) an immunoglobulin, in that order.

Furthermore, working examples describe various embodiments of the subject matter defined in the amended claim 1. One skilled in the art who reads the specification of the instant application would easily understand that applicants were in possession of the conjugate comprising the three components i), ii), and iii) in that order.

Accordingly, it is believed that the claims are fully described in the specification and satisfies the written description requirement under 35 U.S.C. § 112, first paragraph.

Response to Claim Rejections - 35 USC § 102

1. *Rejection over Heavner*

In the Office Action, claims 1-9 and 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Heavner *et al.* (US 2003/0211078, “Heavner”).

Heavner was cited in the previous actions and Applicants' arguments related to the teaching of Heavner are incorporated by reference herein.

In the current Action, the Office asserts that Heavner (at least paragraph [0019]) includes whole immunoglobulins as well as fragments thereof and whole immunoglobulins are not excluded by the disclosure of Heavner.

Applicants respectfully traverse. Heavner teaches a pseudo-antibody comprising an organic moiety (e.g., PEG) covalently coupled to three or more identical target-binding moieties, wherein the target-binding moieties are selected from the group consisting of a protein, a peptide, a peptidomimetic, and a non-peptide molecule that binds to a specific targeted biological molecule. The paragraph [0019] pointed by the Office explains the types of the target-binding moieties.

The subject matter defined in currently amended claim 1 clearly requires that the PEG binds to two different components each at each end of the PEG.

Therefore, the molecules of Heavner fails to teach all and every limitation of the currently presented claim 1. Withdrawal of the rejection is respectfully requested.

2. Rejection over Mohamed

In the Office Action, claims 1-2, 9-10, 15-16, 18-20, and 22 stand rejected under 35 U.S.C. 102(e) as being anticipated by Mohamed *et al.* (US 2006/0153839, "Mohamed"). This rejection is maintained for reasons of record.

Mohamed was cited in the previous Actions, and Applicants' arguments related to the teachings of Mohamed are incorporated herein by reference.

Furthermore, without conceding the rejection, Applicants amend claim 1 to incorporate the limitations of claim 4, rendering the rejection moot.

Accordingly, it is believed that the rejection is not sustainable and withdrawal is respectfully requested.

New Claims 54-57 are Patentable

Claims 54-57, each depend from claim 1, further limit the scope of claim 1. These claims are believed to be allowable for at least the same reasons discussed above for patentability of claim 1.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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